

REMARKS

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested in view of the remarks herewith.

The July 22, 2004 Office Action called for restriction from among the following:

- Group I: Claims 1-21, drawn to a method of increasing the ability of an adenovirus to transduce a specific cell type, comprising the step of modifying a gene encoding an adenoviral capsid protein, wherein said modification increases the ability of said adenovirus to transduce a specific cell type, and a method of killing tumor cells in an individual, comprising the steps of administering to said individual an effective amount of recombinant adenoviruses comprising a therapeutic gene that converts a non-toxic compound to a toxic compound and a gene encoding an adenoviral capsid protein modified by introducing a single chain antibody into said protein, and treating said individual with said non-toxic compound classified in class 435, subclass 320.1; class 424, subclass 93.2, for examples and
- Group II: Claims 22-27, drawn to a method of monitoring the replication and distribution of adenoviral vectors in a subject, said method comprises the steps constructing an adenoviral vector that expresses a fusion protein comprising an adenoviral structural protein and a fluorescent tag, administering said adenoviral vector to said subject, and detecting fluorescence of said vector in said subject, wherein the level of said fluorescence correlates with the level of viral replication and localization of said vector in said subject, classified in class 424, subclass 93.1.

Group I is elected, with traverse, for further prosecution in this application. Applicants reserve the right to file divisional applications to non-elected subject matter. Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional inventions must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions.” *Id.*

Groups I and II are directed to methods of using modified adenoviruses. It is respectfully submitted that any search for the methods of the Group I claims will certainly encompass references for the methods of the Group II claims. The two groups are inextricably linked in that the compositions of both groups are modified adenoviruses. Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine both groups together, as a search for the Group I methods would necessarily include the Group II methods.

In view of the above, reconsideration and withdrawal of the restriction requirement is respectfully requested.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made. Indeed, the search and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner, especially as the claims of all Groups have identical classifications. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction requirement are respectfully requested.

CONCLUSION

In view of the remarks herein, reconsideration and withdrawal of the restriction requirement are requested.

Early and favorable consideration of the application on the merits, and early Allowance of the application are earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: Deborah L. Lu
Thomas J. Kowalski
Reg. No. 32,147
Deborah L. Lu
Reg. No. 50,940
Tel. No. (212) 588-0800
Fax No. (212) 588-0500